PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0147-007.B.WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/CH 03/00048	International filing date *(day/month/year)* 23.01.2003	Priority date *(day/month/year)* 28.01.2002
International Patent Classification (IPC) or both national classification and IPC A61M1/28		
Applicant DEBIOTECH S.A. ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand 25.08.2003	Date of completion of this report 16.04.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Kroeders, M Telephone No. +31 70 340-1967

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CH 03/00048

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-24 received on 16.03.2004 with letter of 16.03.2004

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-24
	No:	Claims	-
Inventive step (IS)	Yes:	Claims	1-24
	No:	Claims	-
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	-

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Document WO-A-9906082, which is considered to represent the most relevant state of the art, discloses (cf. page 6, line 19 to page 16, line 7):

> automatic peritoneal dialysis sampling system (14, 30) adapted to automatically sample at specific time intervals volumetric fractions of dialysate contained in the peritoneum of a patient in order to improve the peritoneal dialysis for a given patient, wherein the peritoneal dialysis sampling system (14, 30) comprises a sampling container (30) and pumping means (P1) disclosed in combination with a series of valves (14, belonging to an automated peritoneal dialysis system) adapted to direct a certain quantity of fluid from a series of containers (S1, S2, G1, M1, M2) to a patient

The subject-matter of claim 1 differs from this disclosure in that the automatic peritoneal sampling system comprises multiple sampling containers and the series of valves are used to fill each of these containers.

In view of said difference, the subject-matter of claim 1 is new and meets the requirements of Article 33(2) PCT.

The differentiating features mentioned above have the purpose of automatically preparing and storing separate samples of dialysate liquid for later analysis.

None of the available prior art documents describes the physical storing of a plurality of dialysate liquid samples for later use, neither before nor after each sample has been analysed.

Therefore, the subject-matter of claim 1 involves an inventive step and the claim meets the requirements of Article 33(3) PCT.

The automatic peritoneal sampling system disclosed in claim 1 is industrial applicable and therefore the requirements of Article 33(4) PCT are met as well.

Claims 2 to 24 depend from claim 1 and refer to further embodiments of the automatic peritoneal sampling system described in claim 1 or a peritoneal dialysis system containing the automatic peritoneal sampling system of claim 1. Thus, claims 2 to 24 meet the requirements of Articles 33(2), (3) and (4) PCT for the same reasons explained above.

Claims

1. Automatic peritoneal dialysis sampling system adapted to automatically sample at specific time intervals volumic fractions of a dialysate contained in the peritoneum of a patient in order to evaluate the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a given patient, said peritoneal dialysis sampling system being characterized by the fact that it comprises a series of sampling containers, pumping means and a series of valves adapted to direct a certain quantity of each fluid sample to a specific sampling container.

2. Peritoneal dialysis system comprising an automatic peritoneal dialysis sampling system according to claim 1, a supplying line and supplying means for supplying dialysis fluid to a peritoneal cavity, a draining line, draining means for draining the fluid from said peritoneal cavity, connecting means for allowing a connection to a Y-site on the draining line which is situated between the patient peritoneum and the draining means of the peritoneal dialysis system.

3. Peritoneal dialysis system according to claim 2 comprising means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences.

4. Peritoneal dialysis system according to claim 2 or 3 comprising means for allowing the use of different peritoneal dialysis liquids and/or different concentrations for each exchange cycle.

5. Peritoneal dialysis system according to any of the previous claims 2 to 7 comprising means for allowing the automatic sampling during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle.

AMENDED SHEET

6. Peritoneal dialysis system according to any of the previous claims 2 to 5 wherein said valves are of electromagnetic type.

7. Peritoneal dialysis system according to any of the previous claims 2 to 6 wherein said pumping means is of a peristaltic type.

8. Peritoneal dialysis system according to any of claims 2 to 4 comprising connecting means for connecting it to the draining line between the draining means and a waste collector in order to collect samples of specific drain cycles.

9. Peritoneal dialysis system according to any of the previous claims 2 to 8 furthermore comprising means for eliminating a volume of liquid between two samplings at least equivalent to the dead volume contained between the patient and the sampling level.

10. Peritoneal dialysis system according to any of the previous claims 2 to 9 furthermore comprising an automatic peritoneal dialysis exchange system, both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system being connected to the patient peritoneum and comprising means for exchanging information together in order for the automatic peritoneal dialysis sampling system to determine the appropriate timing for each sampling on the basis of the dialysis exchange cycles of the automatic peritoneal dialysis exchange system.

11. Peritoneal dialysis system according to the previous claim wherein both automatic peritoneal dialysis sampling system and automatic peritoneal dialysis exchange system are adapted to be synchronized between each other.

12. Peritoneal dialysis system according to any of the previous claims 2 to 11 wherein it comprises a memory key which contains all the necessary data

to program the functioning of said automatic peritoneal dialysis sampling system and to store the sampling information.

13. Peritoneal dialysis system according to any of the previous claims 2 to 12 wherein sampling containers consist of soft pouches.

14. Peritoneal dialysis system according to any of the previous claims 2 to 12 wherein the sampling containers contain vacuum in order to draw the liquid automatically when in open connection with the drawing line.

15. Peritoneal dialysis system according to any of the claims 2 to 12 furthermore comprising means for sequentially collecting sample volumes in a tubing, each sample being separated from the previous one by an air bubble inserted by the automatic peritoneal sampling system in-between each sample.

16. Peritoneal dialysis system according to any of the previous claims 2 to 15 wherein said sampling containers are enclosed inside a cooling box which comprises cooling means to maintain the samples in optimal condition for storage until analysis.

17. Peritoneal dialysis system according to any of the previous claims 2 to 16 comprising analyzing means for directly analyzing of at least one characteristic of the sample in-line, such as by spectroscopy, fluorometry or by use of chemical or electro-chemical means.

18. Peritoneal dialysis system according to the previous claim wherein said analyzing means allows the measurement of at least one of the following constituents or characteristics : glucose, urea, creatinine, Sodium, Chloride, albumine, proteins, osmolarity or ph.

19. Peritoneal dialysis system according to any of the previous claims 17 or 18 comprising means which use the result of the in-line analysis to optimize the next peritoneal dialysis exchange cycle or sampling intervals in order to improve the membrane characteristics evaluation and/or improve the peritoneal dialysis for a specific patient.

20. Peritoneal dialysis system according the previous claim comprising means for defining the specific time intervals for sampling volumic fractions in relation with the peritoneal dialysis program sequences.

21. Peritoneal dialysis system according to any of the claims 2 to 20 comprising means for using different peritoneal dialysis liquids and/or different concentrations for each exchange cycle, whether it is a tidal exchange or a full exchange cycle.

22. Peritoneal dialysis system according to any of the previous claims 2 to 21 comprising means for allowing the automatic sampling to occur during the dwell time of the peritoneal dialysis cycle and/or during the drain cycle in order to improve the evaluation of the peritoneal membrane characteristics and/or improve the peritoneal dialysis for a specific patient.

23. Peritoneal dialysis system according to any of the claims 2 to 22 comprising means for eliminating a volume of liquid at least equivalent to the dead volume contained between the patient and the sampling level between two samplings .

24. Peritoneal dialysis system according to any of the claims 2 to 12 and 15 to 23 comprising means for sequentially collecting the sampling volumes in a tubing and for separating each sample from the previous one by an air bubble inserted by the automatic peritoneal sampling system in-between each sample.